May 9, 2005

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Division of Dockets Management
Food and Drug Administration
Dept. of Health and Human Services
5630 Fishers Lane, rm. 1061, Rockville, MD 20852

McGUFF
PHARMACEUTICALS INC.

Withdrawal of Citizen Petition
Suitability Petition #05P0085

The undersigned wishes to withdraw this petition submitted under 21 CFR 314.93 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to take administrative action based on the guidance provided via telephone by Emily Thakur of FDA who stated that the substitution of a glass vial for an ampoule does not require a suitability petition.

For your reference only, the original action requested was:
Authorization to allow for a deviation in package design from the Reference Listed Drug (Endrate®). Endrate® is packaged in a glass ampoule. MPI petitions to provide a generic form of Endrate® (Edetate Disodium Injection, USP) in a borosilicate, glass, vial (type 1, USP) with a chlorobutyl rubber stopper.

Thank you for your attention in this matter,

Damon P. Jones
McGuff Pharmaceuticals, Inc.
2921 W. MacArthur Blvd., Suite 141
Santa Ana, CA 92704-6929
(714) 918-7277

McGUFF
PHARMACEUTICALS INC.
2921 W. MacArthur Blvd.
Suite 141
Santa Ana, CA 92704-6929
TOLL FREE: 877.444.1133
FAX: 714.438.0536
TOLL FREE FAX:
877.444.1155
FAX: 714.438.0520
EMAIL: answers@mcguff.com

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